

Setting up agile PV operations for a US-based pharmaceutical company

-  **Therapeutic area:** Multiple therapies
-  **Product type:** Drugs
-  **Geography:** US, Europe
-  **Product lifecycle stage:** Post marketing



About the Client

This client is a biotech pharmaceutical company which specializes in the development and commercialization of niche, complex fermentation and semi-synthetic biopharmaceutical products across multiple therapeutic areas. They manufacture over 30 products for immunosuppressant, oncology, antifungal and anti-bacterial indications.

Business Challenge

This biopharmaceutical company had a single immunosuppressant marketed product in the US. The company had limited understanding to set up their pharmacovigilance system and address regulatory requirements. They were seeking immediate support across all PV functions so that they could focus on their market expansion plans.

Overview

A compliant pharmacovigilance (PV) system is vital for pharmaceutical companies intending to market their products globally. It is important that these companies abide by the local and global regulations where they intend to market their products. Meeting varied and sometimes complex regulatory demands is a challenge for pharmaceutical companies. It is especially difficult for small and medium sized companies to manage these safety requirements. The challenges faced by these companies includes the cost of setting up the PV system, lack of available skilled resources, and pressure to market their products given their limited resources in a competitive environment. Typically, small and medium sized companies rely on a specialized safety partner for their end-to-end clinical trials and PV system support. A competent and proactive safety partner can assimilate the necessary product knowledge and apply the necessary processes and services to ensure end-to-end compliance.

Solution

APCER Life Sciences, as their safety partner, initiated the PV setup in a phase-wise manner. A dedicated and highly skilled team was assigned to initiate and execute the project who:

- assessed the current system and implemented improvements to ensure audit-readiness;
- engaged a shared services team of experts and operators across PV functions (case processing, literature, signal management);
- worked on to setup a compliant safety database within 6 weeks;
- initiated knowledge transfer that included APCER training the customer's in-house team on basic PV and database usage; and
- supported them for complex activities such as REMS preparation and submission.

With the inception of the project, the cases were triaged, processed, and submitted per the regulatory requirements.

Outcome

- Setup of an efficient PV system for timely submission of cases
- Set-up of cost-effective and agile PV operations
- On-demand advisory for compliance to dynamic regulatory changes
- Enabling the company to focus on its market expansion objectives

APCER pharmacovigilance capabilities



Risk management expertise: Risk management solutions provided by our experts and QPPVs are core to our governance model and project oversight.



Efficient project management: Our unique "two-in-a-box model" deploys a Client Partner and Delivery Head to ensure timely execution on deliverables and inculcate strong governance to monitor compliance at each stage through the life of the project.



A proactive approach toward service-level adherence (SLA) and quality deliverables, coupled with strategic alignment to provide business value, makes us a trusted partner for PV for this US-based pharmaceutical company.

Together for better health

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

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